

# Guidelines for Preventing Medication Errors in Pediatrics



*J Pediatr Pharmacol Ther 2001;6:426-42*

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The Pediatric Pharmacy Advocacy Group is a non-profit professional pharmacy association dedicated to improving the healthcare of all children. The sole purpose of PPAG is to advocate for safe and effective medication use in children through communication, education, and the promotion of research.



The Institute for Safe Medication Practices is a nonprofit healthcare agency comprised of pharmacists, nurses, and physicians. Founded in 1994, the organization is dedicated to learning about medication errors, understanding their system-based causes, and disseminating practical recommendations that can help healthcare providers, consumers, and the pharmaceutical industry prevent errors.

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## REVIEW

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### Guidelines for preventing medication errors in pediatrics

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Medication errors commonly occur in healthcare facilities. Most literature has centered on medication errors and prevention of those errors in facilities that care primarily for adults. This article concentrates on the medication errors that are common to pediatrics facilities, and recommends strategies for reducing the potential for medication errors in those settings. Methods reviewed include looking at system deficiencies vs. the single practitioner, education programs that reduce the risk of error, strategies for reducing the potential of medication errors, use of automation, and benefits of a computerized prescriber order entry system.

**Key words:** Medication errors, patient safety, medication safety, pediatrics, computerized prescriber order entry, automated dispensing devices, prescriptions

(*J Pediatr Pharmacol Ther* 2001;6:427-43)

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In August 1998 the draft guidelines were published in the *Journal of Pediatric Pharmacy Practice*.<sup>1</sup> In order to stimulate discussion on the topic of preventing errors in the pediatric population and to refine the draft guidelines this manuscript was written as a collaborative effort between the Institute for Safe Medication Practices (ISMP) and the Pediatric Pharmacy Advocacy Group (PPAG). The following are the results of that effort and represent the recommendations of these two organizations.

Medication error prevention is fundamental in the care of all patients. Although many medication errors go unreported and are often undetected with minimal clinical significance, some medication errors do result in serious morbidity or mortality. Certain patient populations are exposed, by inherent characteristics, to greater

risk of medication error occurrence and increased potential for morbidity. The pediatric population is a high-risk group because the number of potential adverse drug events is three times that found in hospitalized adult patients.<sup>1</sup> Factors placing pediatric patients at increased risk for adverse drug reactions can be found in Table 1.<sup>3-9</sup>

The special treatment considerations of this population provided impetus for a collaboration between the ISMP and the PPAG. A symposium was held prior to the 1997 American Society of Health System Pharmacists Mid-year Clinical Meeting in Atlanta, Georgia. This meeting included members of the ISMP and PPAG, as well as a panel of experts in the field. In hopes of avoiding or decreasing the occurrence of future medication errors in the pediatric pop-

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**Table 1.** Factors placing pediatric patients at increased risk for adverse drug reactions<sup>3-9</sup>

- Different and changing pharmacokinetic parameters between patients at various ages and stages of maturational development.<sup>10</sup>
- Need for calculation of individualized doses based on the patient's age, weight (mg/kg), body surface area (mg/m<sup>2</sup>), and clinical condition.
- Lack of available dosage forms and concentrations appropriate for administration to neonates, infants, and children. Frequently, dosage formulations are extemporaneously compounded and lack stability, compatibility, or bioavailability data.
- Need for precise dose measurement and appropriate drug delivery systems
- Lack of published information or FDA-approved labeling regarding dosing, pharmacokinetics, safety, efficacy, and clinical use of drugs in the pediatric population.

FDA=Food and Drug Administration

ulation, this group discussed challenges involved in medication error prevention in neonates, infants, and children and addressed methods to overcome these challenges. The session was audio taped and later reviewed in order to incorporate salient points into this document.

Recommendations for the prevention of medication errors in the general hospitalized population<sup>11</sup> and in patients receiving cancer chemotherapy<sup>12</sup> have been published elsewhere. While many previously published recommendations apply to the pediatric population, this document focuses exclusively on this select patient group and offers specific recommendations for the prevention of medication errors. Some of the recommendations presented in this document may reiterate those published in previous documents. The purpose of this document is to recommend medication error prevention strategies for consideration in the development of: 1) organizational systems (e.g, computerized order entry systems, automated dispensing systems, bar coding, robotics); 2) educational systems; and 3) manufacturing and regulatory systems. The paper will also suggest medication error prevention strategies for individual healthcare professionals.

## ORGANIZATIONAL SYSTEM RECOMMENDATIONS

Medication errors rarely occur from the failure of a single element or because of mistakes by single practitioner. Rather, medication errors are the result of the combined effects of "latent failures" in the system and "active failures" by indi-

viduals. Latent failures are weaknesses in the structure of an organization, such as faulty information management or ineffective personnel training, which result from both good- and ill-conceived decisions. By themselves, latent failures are often subtle and may cause no problems. Their consequences are hidden, becoming apparent only when they occur in proper sequence and are combined with active failures of individuals to penetrate or bypass the system's safety nets. Many of the latent and active failures that were at the root of medication errors are not apparent until a root cause analysis is performed.<sup>13</sup> For this reason, providing an optimal level of medication safety requires both recognition and correction of latent failures in the system. This document looks beyond blaming individuals and focuses on the multiple underlying system enhancements that can shape individual behavior and create the conditions whereby medication errors may be prevented. It is unrealistic to expect absolute perfection or error-free performance from any person. For this reason, it is essential that systems be established to minimize the risk of medication errors. In order to increase the number of opportunities to detect and prevent medication errors, these systems should be highly redundant and should be updated as new potential sources of error are identified. In the post-medication error evaluation process, system deficiencies should be identified and corrected before placing all responsibility on human error.

### Computerized Order Entry System Recommendations

Every healthcare provider has an occasional "bad day" or lapse in personal performance that could result in a medication error. For this reason, available technology should be used, especially in situations where accuracy is critical. In healthcare, computers can provide technological support by providing information, facilitating clear and accurate communication, alerting the user to potential errors, and processing data. The selection and programming of a computer system should be done with medication error prevention in mind. The computerized order entry process will act as a firewall, which can reduce the risk of medication errors that subsequently occur in patients. A variety of functions should be incorporated into the "ideal" computer order entry system (Table 2).

Another item that should be considered involves site-specific programming choices, which can make a system more helpful in the prevention of medication errors. These systems

should use only metric units and institution-approved standardized doses and concentrations. All decimal expressions less than one whole unit should be preceded by a leading zero (i.e., 0.1 not .1) and whole numbers should not be followed by a trailing zero (1 mg not 1.0 mg).<sup>14</sup> The use of abbreviations for drug names should not be permitted. There should be an established link to data entry requiring input of up-to-date patient information (e.g., age, weight (in kilograms), allergies, diagnosis). The software should also screen for allergies, large or small dosages, and drug-drug, drug-nutrient, or drug-disease interactions and should sound or flash an alert when a potential problem is identified. For more serious warnings, a manual over-ride should be required and should be accompanied by appropriate documentation. Caution should be exercised to avoid manual over-rides for minor problems because this promotes automatic manual over-riding that could lead to a failure to appreciate the significance of the alert. Finally, there should be a set and utilize minimum and maximum dose range based on pediatric age, weight, and height

**Table 2.** Functions important to the "ideal" computer order entry system

- Prescriber order entry for verification by nurse and pharmacist
- Computer-generated medication administration records from a common data base shared with the pharmacy and the prescriber
- For each patient, lists of current medications that are readily accessible by caregivers
- Two-way interface between the pharmacy and other institutional systems (e.g., laboratory, admission and discharge, clinical records)
- Access to historical patient data (i.e., archived information)
- Ability to calculate and verify appropriate height-weight range and dosage for patient
- Access to vital patient and drug information directly from order entry, medication profile, and medication administration screens
- Ability of system to use patient and drug information to provide unsolicited information during order entry to reduce potential for adverse drug events (e.g., drug interactions, contraindications, excessive doses, allergies). This should be part of a comprehensive decision support program. These programs would include checking for laboratory results and advising the prescriber of the need for dosing modifications for specified medications. Automatic checking should also include drug-drug interactions, drug-nutrient interactions, drug duplication, therapeutic duplication, contraindicated medications, weight-based dosage checking
- Provide a forced function by limiting the route and frequency by which a drug is ordered

parameters. Prescriber care sets may also be linked to patient weight in selecting drug dosages. Where applicable, the software should include set dose limits for single doses, 24-hour doses, course of therapy, and lifetime doses. The system should also contain a built-in growth chart to alert the user to obvious patient outliers.<sup>15</sup>

Because of the potential for selecting the wrong medication mnemonics should not be used. If it is determined by an organization to employ mnemonics, then caution should be used in selecting mnemonics, ensuring that: 1) no two mnemonics are so similar as to promote selection errors by bringing dissimilar items onto the screen at the same time; 2) separate selections are available for intravenous products which are given by a different route. For example, a separate computer file should exist for amphotericin B intranasal administration versus intravenous administration to prevent IV administration of the intranasal dosage form; and 3) potentially misleading abbreviations are not incorporated in the mnemonics.

The final item important in site-specific programming choices involves the selection of labels and label set-up programs. These systems should ensure that:

- labels are easy to read
- all vital information is included and extraneous information is excluded
- the most important information is emphasized through typeface and placement (e.g., patient name, drug name, concentration, dose, and route)
- appropriate spacing is used between terms
- laser printers are used in order to provide the greatest clarity
- leading zeros are used (0.1 mg) and trailing zeros are omitted (1.0 mg)
- dangerous abbreviations are not used.<sup>10</sup>

Computerized prescriber order entry systems are one of the many tools that are used as a method of medication error reduction. No one device or technology will eliminate all errors. It is only through the coordinated use of elements of a medication error reduction strategy that we can improve the safety of our patients.

### *Automated Dispensing Systems Recommendations*

In addition to computerized prescriber order entry, there are several other technologies available to today's healthcare system. While there are some timesaving elements associated with technologies, it is important to review their potential for errors in the pediatric population.

Automated dispensing devices (ADD) have become very common technology. They are designed to reduce some of the staffing burdens and allow for reassignment of staff to provide clinical services. While this may be true in some hospitals, implementation of this technology may decrease the use of traditional methods that are employed to enhance safety and may actually increase the number of medication errors. Several issues must be in place before ADDs are used (Table 3).

Bar code technology is moving to the patient bedside and can help assure that the right drug, correct time, precise dosage and right patient are selected. It can also document the identity of the person administering the medication. Because a standardized Universal Product Code (UPC) has not been created for the dose level, bar code labels must be prepared for each distinct unit dose.

Robotics for centralized automated dispensing has increased over the last few years. As with the ADD, care must be taken not to move away from the unit dosing of medications for the pediatric population. In some cases, standardized doses can be employed to help implement and use the robotic technology in the pediatric setting.

### *Other System Recommendations*

While our recommendations apply primarily to the provision of healthcare in the institutional setting, some of the general ideas and principles may be adapted for use in other practice settings. Institutions dedicated solely to the treatment of pediatric patients may find it easier to create and enforce policies and procedures directed toward the prevention of medication errors in this specific population, but all facilities involved in the treatment of pediatric patients should assume the responsibility for identifying and implementing

**Table 3.** Issues to consider before ADDs are used

- The ADD must interface with the pharmacy computer system and should allow the pharmacist to review the new order prior to release into the database. The review must also precede release of any medication from the ADD. This can be accomplished by a profiling interfacing system that allows the pharmacist to enter all new orders into the pharmacy system before a nurse has access to the medications in the ADD. Although some ADDs send information to the pharmacy system, they do not alert the pharmacy that a medication has been released for administration to a patient.
- An override exists in all ADD. The override function must be addressed at the time of implementation and should be restricted to true “emergencies.” If a liberal approach is used and the function becomes one of convenience and not one of emergency, many errors will be allowed to occur prior to pharmacist review. Even during emergencies the pharmacist should be alerted to the incident. As stated above, some systems will send information to the pharmacy system; however, they do not alert the pharmacy that a medication has been released for administration to a patient. Alternatively, during emergencies a second nurse could verify the order before administration to a patient. All overridden reports should be routinely checked for patterns.
- The use of ADD in the pediatric setting may also decrease the use of patient-specific unit doses. While these machines may contain commercial unit dose containers, they are not specific to that patient and act as bulk containers. Nurses are required to calculate doses and draw up medications, and another practitioner must verify the dose before administration.
- Stocks in each ADD can be tailored to specific patient care units to assure that medications that are unfamiliar to a practitioner cannot be removed in error. Careful drug selection based on the needs of the patient care unit, patient age, diagnosis, and staff expertise should be used to tailor each unit.
- Use of an ADD with specific cells for each drug are available only when the patient is receiving that medication at the correct time. Systems that provide open drawer technology increase the risk of selection of the wrong medication or provide an opportunity for a medication to inadvertently fall into the wrong container.
- A system should be in place to ensure the pharmacist has verified the placement of medication after restocking or that there is bar code technology to verify placement.
- With the addition of an ADD there are now an increasing number of locations where medications can be stored. Multiple locations often result in an increase in the number of missing medications. Missing medications result in delays for patients and may result in multiple doses being administered.
- Some additional recommendations include: 1) minimize variety; 2) stock unit dose drugs in the smallest dose/container size available; 3) supply only a single concentration of medication; 4) establish maximum dose ranges for high-alert drugs; 5) returns should be made to the pharmacy and not to the ADD, unless there is a specific return bin within the ADD dedicated to returned drugs; and 5) use of allergy reminders as needed.

ADD=Automatic dispensing device

measures necessary to protect this population from medication errors.

A strong formulary system that is governed by the Pharmacy and Therapeutics (P & T) Committee should be operational and should consist of physicians, pharmacists, nurses, risk managers, and other healthcare professionals. If the facility is not dedicated entirely to the treatment of pediatric patients, the departments should ensure sufficient representation of all disciplines within this specialty on the P & T Committee. Alternatively, a subcommittee of the P & T Committee could be appointed to consider and make recommendations regarding pediatric

formulary considerations. The committee should create and enforce policies regarding evaluation, selection, prescribing, and use of drugs and devices for pediatric patients within the organized health care setting (Table 4). Likewise, the committee should establish standardized dosing, medication concentrations, drug administration schedules, and abbreviations. The committee should also encourage the use of metric units of measurement and the rounding of odd doses.

It is also imperative that policies and procedures are developed to ensure adequate personnel selection, training, supervision, and evaluation. These policies and procedures should

**Table 4.** Formulary management

The P&T Committee should:

- ensure that drugs are appropriate for use in the pediatric population (e.g., concentrations, dosage forms, inactive ingredients).
- guarantee that all devices (e.g., pumps, compounding devices, burette chambers) selected for use are appropriate for the pediatric population. Procedures for appropriate use of all institutionally accepted medication administration devices (i.e., enteral and parenteral) should be detailed and distributed to all patient care areas. These procedures should be delivery system specific and, when appropriate, drug and/or administration route specific.<sup>6,8,16,17</sup> The ability of a device or set to permit free-flow should be evaluated prior to acceptance.
- make certain that special oral syringes used within the institution are not compatible with needles and needleless IV systems or parenteral catheters.
- ensure that appropriate measuring devices should be available for oral administration and parameters should be set to address minimum measurable volumes for these devices (i.e., measuring 0.2 mL in a 10 mL syringe).
- ensure that at the time of formulary review potential medication errors are evaluated. The committee should determine if the medication: 1) sounds (i.e., verbal order confusion) or looks (i.e., written order confusion) like another drug on formulary; 2) uses packaging that appears similar to other drugs on formulary; 3) requires the performance of certain tests as part of monitoring to assure safety; 4) is associated with clearly defined dosing information; and 5) allows for standardized dosing that can be used in order to decrease the number of calculations required.
- approve clinical pathways, protocols, preprinted orders, dose calculation forms, etc. via a multidisciplinary team or the committee should appoint and oversee a multidisciplinary team for this purpose.
- be involved in computer software and ADD decisions.
- review methods for ordering total parenteral nutrition and limit choices to mg/kg/day for younger children and per liter for older children.

*P&T = Pharmacy and Therapeutics Committee; ADD = automated dispensing devices*

include proper interviewing procedures, staff orientation and development programs (including the discussion of medication errors), and should consist of regular (annual, biannual) age-related competency evaluations that include calculation skills and opportunities for continuing education specific to pediatrics.<sup>18-22</sup> While it is essential that personnel who regularly serve this patient population be well trained and competent, it is very important that personnel who work with this population less frequently be competent; therefore, these personnel should also be required to participate in any training and competency evaluations required of regular employees in this area. These policies and procedures should also establish reasonable workload levels and working hours and ensure, through adequate staffing, that these quotas are rarely exceeded.

The work environment where drugs are prepared or administered should be free of potential factors that contribute to medication errors. These include high noise or traffic, poor lighting, temperature extremes, and distractions or interruptions.

A unit dose dispensing system should be in place and the pharmacy department, should prepare and dispense individual patient doses in ready-to-administer form to minimize the need for manipulation of drug products outside of the pharmacy.<sup>3,8,20</sup> In order to facilitate communication and exchange of information among the healthcare team, pharmacists should be as accessible as possible, participating in patient rounds and/or working in or near patient care areas.

A highly redundant system of checks should be instituted for the entire medication delivery process from ordering of the medication, to preparation and dispensing of the drug, to administration of the medication. This would provide numerous opportunities for the discovery of potential medication errors before they reach the patient.<sup>23,24</sup> Documentation of any required change or alteration in medicinal therapy is also very important. The system should provide for review and verification of the prescriber's original order prior to the dispensing of the drug (except in emergency situations). To prevent the occurrence of drug administration without appropriate review, floor stock should be

eliminated or limited to very low risk medications or automated dispensing modules should be available and all orders should be screened by a pharmacist.<sup>14,21</sup>

With the increasing use of automated dispensing devices pharmacists have lost some control over medication dispensing. A feature available on many automated dispensing systems can, and should, be used to minimize the potential error to patients receiving a high-risk drug prior to appropriate order review and verification. This feature enables a lock to be placed on selected drugs so that they cannot be retrieved from the machine until the order has been screened and their dispensing has been authorized.<sup>14</sup>

In children's hospitals, the standard of care calls for 24-hour pharmacy operation.<sup>3</sup> In other hospitals with pediatric patients, selected medications should be available in a designated area when a pharmacist does not provide 24-hour pharmacy services and automated dispensing systems are not in use. After-hours when the pharmacy is closed, pharmacy access by non-pharmacy personnel is deemed unsafe and unacceptable. In addition, when 24-hour pharmacy service is not provided, a pharmacist should be available "on-call" to answer questions and prepare medications as necessary.

Another potential source for error involves verbal ordering. This practice should be avoided whenever possible. Policies and procedures should be established and should specify acceptable circumstances for this practice and personnel permitted to accept this type of order. Directive to repeat back the order for verification and clear requirements for documentation of these orders, including the time frame in which the prescriber must verify and sign the order should be included in the policies. The use of computerized prescriber order entry, approved and preprinted orders, and facsimile transmission of orders should be used to the maximum extent possible to eliminate verbal ordering.

Clear and accurate labeling of all drug and nutrition products is very important. Labels should clearly express all pertinent information required for verification of contents by other healthcare professionals. Auxiliary labels should also be used in situations where they might

emphasize an important aspect of the product.

With respect to the safe use of medications, there should be an ongoing, multidisciplinary program of quality improvement and peer review that includes a formal drug-use evaluation program, and a system for monitoring, reporting, and reviewing medication errors. Policies should be established that not only eliminate the fear of reporting errors, but encourage an increased discussion of errors that have occurred in-house and elsewhere in the practice of medicine.<sup>21</sup> A newsletter or other hospital- or department-wide publication should be created for the dissemination of this information.<sup>23</sup> One of the most important methods for preventing adverse drug events is for institutions to seek and use knowledge from other institutions that have already solved similar problems. Staff should regularly monitor publications such as the ISMP Medication Safety Alert!, the FDA Medical Bulletin, and other publications that contain such information. Ultimately, there should be a mechanism to provide feedback to all staff members on current and common types of medication errors within their healthcare system. In those facilities with medical residents, it is beneficial to establish a relationship with the chief residents and incorporate medication error reduction strategies within the resident training curriculum.

All healthcare workers involved in patient care should have ready access to appropriate and current clinical information about patients (e.g., weight, medications, allergies, diagnoses, laboratory values) to aid in the appropriate selection of medications, calculation of doses, and evaluation of orders. Current references should be easily accessible when they are need and should be located through out the facility. These references should include Internet access to medical information, texts and publications, and institution-specific resources. Information available in the references should include appropriate uses of the medication, precautions, drug-drug interactions, drug-nutrient interactions, adverse effects, instructions for administration or infusion methods, usual doses, and patient information and instructions.<sup>10</sup> Expired texts must not be used for routine drug information because updated information or corrections of previous errors will not

be available. Computerized up to date drug information systems (i.e., CD-ROM), such as Micromedex<sup>®</sup> or Facts and Comparisons<sup>®</sup> should be available to healthcare providers for ease of access to current information. Centrally updated computerized systems have the advantage of limiting the availability of outdated references and providing timelier updating of information. Institution-specific references should be created, incorporating standardized doses accepted by the institution, standardized concentrations available within the institution, and osmolality information for intravenous and oral medications.<sup>7,25</sup> Other institution-specific information, such as restrictions on prescribing or administration imposed by hospital policy may also be included.<sup>7,25</sup> These references should be available in all areas where medications are prescribed, prepared, monitored, and administered, and as a pocket-sized version (hardcopy or electronic) for convenient carrying.<sup>23</sup>

A critical care drug (emergency medication) dosage calculation sheet should be completed and required for each pediatric critical care patient. Standard sheets for a spectrum of weights should be available as a reference in the event that a patient requires emergency treatment prior to the completion of their individualized dosage sheet.<sup>26,27</sup>

Policies should be established that require documentation of the actual time of medication administration, rather than simply documenting administration, which can lead to the assumption that every dose is administered exactly on schedule. Where appropriate, method of administration should also be recorded. Newer technologies will allow for the electronic documentation of administration. Precise information facilitates accurate interpretation of laboratory data, pharmacokinetic calculations, and appropriate dose and/or interval adjustments.<sup>4,28</sup>

## EDUCATIONAL SYSTEM RECOMMENDATIONS

An early step toward the prevention of medication errors is the education of healthcare professionals involved in medication prescribing, preparation, labeling, dispensing, monitoring, and administration. Training programs for all

**Table 5.** Suggested components for training programs for all healthcare professionals

*Training programs for all healthcare professionals should include:*

- courses to build and reinforce communication skills among healthcare professionals and improve communication with patients and their caregivers. It is important for all healthcare professionals to learn the real potential for human error<sup>23</sup> and to recognize the need to function as a team using each other as resources to achieve optimal patient care. Instruction in medication error prevention should also be included at the earliest levels of all healthcare training programs and as part of orientation programs within each organized healthcare facility.
- instruction and practice in performing the mathematical calculations used in patient care. Testing should be performed to assure that common causes of medication errors are recognized and understood. This includes unit conversions, calculations of dose, calorie and fluid requirements, and dosing intervals, and pharmacokinetic calculations. With more practice comes greater confidence and fewer errors.<sup>18,26,30</sup> Errors involving 10-fold over- or under-doses are common. Other common errors involve calculating intravenous (IV) infusion rates, using a daily dose as the individual dose or dividing a daily dose by the time interval instead of the number of times to be administered per day (i.e., dividing a daily dose by 6 for an every six hour schedule).
- extensive education regarding patient populations such as pediatric patients with special needs and treatment considerations.<sup>3</sup>
- instruction and education with regard to patient monitoring. Health care providers should be skilled in interpretation of laboratory data, physical signs and symptoms, and adverse drug reaction recognition and reporting.

healthcare professionals should include a variety of items on errors (Table 5).<sup>30</sup>

In order for physicians to be prepared to enter practice their training should include instruction in the basic requirements of prescription writing. They should know that every prescription should be printed legibly and should contain a variety of information (Table 6). At a minimum, items to be included on the prescription include the patient's name, date of birth, current weight, allergies, and any additional patient-specific data appropriate to the circumstance. In addition, generic drug name, drug strength or concentration, dose volume expressed in metric units dosage form, quantity to be dispensed expressed in metric units, complete directions for use including dose, any calculations used in determining the dose, route of administration, and frequency of dosing, purpose of the drug, the number of authorized refills or intended duration of therapy, and prescriber's name should be included with each prescription. Additionally, instruction should address what not to incorporate in a prescription (e.g., certain dangerous

abbreviations, leading and trailing zeros).<sup>9-11</sup> These practices would save physicians time, as well as the time of other healthcare professionals, and help avoid medication errors.<sup>26,30</sup>

### *Writing Discharge Prescriptions*

Continuity of care is a method of reducing potential medication errors. Almost 70% of hospital admissions related to adverse drug events are associated with patient compliance.<sup>33</sup> Clear directions for the patient or caregiver, as well as the community pharmacist or nurse will assist in increasing compliance. Continuity begins with the prescription. Elements of a prescription are depicted in Table 6.

### **MANUFACTURING AND REGULATORY SYSTEMS**

Historically, pharmaceutical manufacturers have rarely conducted research in the pediatric population. This lack of research occurs of a variety of reasons including liability concerns, greater

**Table 6.** Recommended elements of a prescription

- Patient's full name
- Patient's age (date of birth) and current weight
- Information regarding diagnosis and other patient-specific data appropriate to the circumstance should be included.
- Any known allergies should be included.
- Drug name, dosage form, and drug strength. If the medication is rarely used, the name should be print. Concentration should be expressed in metric units.
- Number or amount to be dispensed. If appropriate, quantity to be dispensed should be expressed in metric units.
- Include calculations, or at least mg/kg/day dosing, so calculation can be independently double-checked (i.e., amoxicillin 40mg po q 8 hrs (40mg/kg/day).
- The prescriber's name and pager or telephone number should be included.<sup>30</sup>
- Complete instructions for the patient including indication (i.e., purpose of the drug), directions for use including dose, frequency of dosing route of administration, intended duration of therapy, and the number of authorized refills.
- Products to be administered by the patient or caregiver in the outpatient environment should be labeled expressing the dose in convenient units of measure. Listing equivalent measurements may be helpful to clarify the intended dose (i.e., 1 teaspoonful (5 mL) by mouth twice daily).
- During discharge counseling, patients and/or caregivers should be asked to demonstrate the measurement of a dose if medications are dispensed in liquid form. They should also be asked to demonstrate any manipulation of a commercially available dosage form and the administration of a dose if special techniques are required (i.e., injection, nebulizer, or inhaler). Appropriate measuring devices should be provided or recommended. Where possible, the actual measuring device should be demonstrated. Written education materials should provide relevant information in a clear, easily understood format.<sup>31,32</sup> The use of household teaspoons and tablespoons should be discouraged because of their variability and resulting inaccuracies.

investments of time and money to conduct clinical trials in this population, and (perhaps most significantly), a limited economic return because this population comprises only a small portion of the pharmaceutical market. The lack of pediatric research by pharmaceutical manufacturers has resulted in the majority of drugs entering the market and being used "off-label" in neonates, infants, or children with little or no dosing, pharmacokinetic, safety, efficacy, or clinical data. Pharmaceutical manufacturers and FDA have become increasingly aware of the challenges facing pediatric healthcare professionals. Although this population has long been recognized as unique and referred to as "therapeutic orphans,"

only recently have changes have occurred that now require new medications to be evaluated in pediatric patients.<sup>34</sup>

In addition to guidelines published previously for pharmaceutical manufacturers and regulatory agencies regarding the naming, labeling, and packaging of drug products, the following are recommended:

1. More research should be conducted in pediatric patients to determine safety and efficacy in neonates, infants, and children. There should be established pediatric dosage guidelines, including the dosing adjustments required for renal and hepatic dysfunction. The industry should identify pediatric-specific

- ic adverse drug reactions and should include information in 'a' through 'e' in the official product labeling. Formulate standard guidelines must be in place for the extemporaneous compounding of pediatric dosage forms from commercially available dosage forms when necessary. These guidelines must include data regarding product stability, compatibility, and bioavailability. Companies should also develop drug delivery devices and infusion systems appropriate for pediatric patients of all ages.
2. Increase commercially available pediatric dosage forms, especially for those drug products with pediatric indications. This would ensure that dosage form and concentration are appropriate for the pediatric population and intended route of administration and would facilitate accurate measurement of doses.<sup>3,8,17</sup> Dose volumes of oral liquids and intravenous medications should be large enough to measure accurately, but not too large to create a medication administration challenge. Oral products should be available in palatability of dosage forms. Finally, appropriateness of all ingredients, including inactive ingredients (e.g., preservatives such as benzyl alcohol) should be considered.<sup>3,8,10,17</sup>
  3. Because look-alike products may lead to medication errors, similar proprietary appearances of packaging and labeling should be avoided for both prescription and non-prescription drug products.
  4. Look-alike or sound-alike trademarked and generic names, as well as brand name line extensions, should be avoided for prescription and non-prescription drug products, including store or generic brand over-the-counter products. What is known as "tall-man lettering" should be utilized to distinguish medications with similar looking brand and generic names (i.e., hydrOXYzine vs. hydrALAZine).
  5. Manufacturers should employ failure mode and effects analysis or similar techniques that require practitioners to systematically assess the potential for error with packaging, labeling, and nomenclature prior to market launch.<sup>13</sup>
  6. Standardization of uniform bar coding that would be compatible with computer systems used in organized healthcare settings should be developed.
  7. Standardization of calcium, zinc, and iron product concentrations should occur.<sup>9</sup> This might include standardizing the ordering of these products to milliequivalents, millimoles or milligrams of the elemental product.
  8. Healthcare professionals should be informed about new drugs and their indications using unbiased information and educational programs. At a minimum, education should include indications for use, adverse drug reactions, and drug-drug and drug-nutrient interactions.
  9. Labeling of non-prescription medications must clearly differentiate between multiple concentrations. It should also provide clear warnings, and usage and dosing information for patients and caregivers.<sup>35</sup> Dosage information should be expressed as units of measure that correspond to the calibration on the dosing device. Information should be included that warns that the measuring device does not necessarily represent one dose. Ideally, dosing devices should be calibrated in only one system of measure, preferably the metric system, contain no abbreviations, and be marked in a contrasting color.<sup>36</sup>

## HEALTHCARE PROFESSIONALS

Although errors are most often due to system deficiencies or failure, individual healthcare professionals also play a role in the prevention of medication errors. Every healthcare professional should accept responsibility for providing his or her patients with the best care possible by:<sup>37</sup>

1. keeping informed of medical knowledge, especially as it pertains to the treatment of pediatric patients through review of the medical literature review, continuing education programs, and communication with other healthcare professionals.
2. actively participating as a member of the patient care team, sharing information, welcoming the input of colleagues, and being involved in staff development and education

- programs.
3. carefully performing and double-checking calculations to ensure correctness.<sup>19,20</sup>
  4. consulting literature, references, and/or colleagues when unsure of appropriate prescription, preparation, or administration of a drug product or pediatric treatment requirements.
  5. ascertaining that all pertinent patient information is available and current so that a patient's total status and appropriateness of therapy can be evaluated.
  6. focusing on a single task, avoiding distractions and interruptions whenever possible, to maintain concentration.
  7. participating in multidisciplinary committees to improve system functions.

### *Recommendations for Prescribers*

The first individual who can take steps to prevent the occurrence of a medication error is the prescriber. Drug orders should be legible. Direct prescriber computer order entry is preferable and should be used by all institutions and all prescribers.<sup>38</sup> Handwritten prescriptions or orders increase the occurrence of transcription errors and fail to utilize the information and safety checks available via the computer system. When prescriber computer order entry is not available, prescribers with poor handwriting should print or type medication orders. Preprinted orders are another option for the prescriber with poor handwriting; however, a multidisciplinary team of the P&T Committee must approve these.

Drug orders should be complete and should include the components described in Table 6. Likewise, prescribers should also adopt the following measures to ensure that the clear intent of the order is communicated.

1. Drug name should be either the official (generic) or trademarked name clearly spelled. For those medications that contain multiple ingredients, the use of the trade name is more appropriate. When the trade name is used, the generic ingredients should also be listed on the label. Abbreviations of the name, acronyms, and chemical or locally coined names should not be used because they might be misunderstood.
2. Instructions should be written out, rather than expressed using abbreviations that are ambiguous or not approved within the institution.
3. Vague instructions, such as "take as directed," should not be used.
4. Because many medications are available in varying strengths or concentrations, dosage strengths or concentrations and volumes should be expressed in exact metric units (e.g., mg, units), rather than dosage form units (e.g., # tablets, vials, ampules, capsules, mL).
5. A leading zero should always precede decimal expressions less than one (i.e., 0.1 mg), but a trailing zero should never follow a whole number (i.e., 1.0 mg).
6. To facilitate verification of the appropriateness of the dose by other healthcare professionals, any calculations used in determining the dose should be included in the medication order.
7. For medications other than most topically administered, both the calculated dose AND the mg/kg or mg/m<sup>2</sup> dose upon which the dose is based should appear in all medication orders for pediatric patients. This simple step helps assure that a nurse and/or pharmacist do not misread an order. It also promotes accurate dose calculation by facilitating redundant checks by nurses and pharmacists.
8. If the order is for a drug product that is not on formulary or for a new dosage of a formulary medication, the prescriber should provide information with the order or in the patient's chart for other healthcare professionals. Use of a non-formulary medication introduces a new drug into the system that healthcare professionals may not recognize; thereby, increasing the risk of error. A healthcare provider may assume that it is another drug that sounds, or looks similar to an agent with which they are familiar. Use of non-formulary items should be limited for the above reasons.
9. If doses are changed for an ambulatory patient, new prescriptions should be written and remaining refills of previous doses should be canceled. This information should

be communicated to the pharmacy providing outpatient services.

In situations where the use of verbal prescriptions or orders is necessary, the prescriber should dictate the order slowly and clearly, spelling the drug name and any other words that may be misheard. Likewise, the prescriber should restate numbers that may be confused (i.e., 15 as "one five"). In order to verify accuracy, the prescriber should have the recipient repeat the order back to him or her. The prescriber should also be certain to verify the transcribed order within a designated time frame.<sup>36</sup>

When possible, without compromising patient care, odd dosages should be rounded-off for more convenient and accurate measurement. When appropriate, prescribers should write orders for commercially available drug products, rather than dosage forms prepared by manipulation of commercially available products. If at all possible, drugs should be prescribed for oral administration, rather than by injection. Prescribers should consider consolidating styles of managing patients. A variety of ways of managing a patient's medical condition are possible and are considered good medicine that is cost effective. However, diversity in writing medication orders may lead to confusion and errors. Consolidating styles in an intensive care unit setting so that all drips are written as either mcg/kg/minute or mg/kg/hour can avoid calculation errors that occur secondary to moving back and forth between systems.

The prescriber should also counsel the patient and his or her caregiver, familiarizing them with the name, indication, route of administration, dose, dose frequency, potential adverse effects, and how adverse effects might be managed for each medication the patient is receiving.

### **Recommendations for Pharmacists**

Because of their specialized knowledge of medications and their role in the drug distribution process, pharmacists are in a unique position to prevent medication errors and ensure appropriate medication use. Pharmacists should interact with other members of the healthcare team to develop, implement, and monitor a therapeutic

plan to achieve optimal care for each individual patient, making efforts to detect and resolve drug-related problems before they reach the patient. Pharmacists must also pay close attention to their portion of the drug distribution process, carefully reviewing prescriptions and preparing and dispensing medications, while serving as the drug information specialist. Suggestions that may assist pharmacists in preventing medication errors while fulfilling these responsibilities are found in Table 7.

Prior to patient discharge, the pharmacist and/or nurse should make certain that patients and/or their caregivers have all the necessary drug information and knowledge to correctly measure and administer doses. It is also imperative that they have appropriate equipment for correct measurement and administration of the prescribed dose. The patient and/or caregiver should also be asked to demonstrate how they would prepare and administer doses to verify that they are prepared to perform these tasks. If problems or difficulties are exposed, further counseling and teaching are in order.

### **Recommendations for Nurses**

Nurses are in a position too not only identify prescribing and dispensing errors, but to prevent these errors from reaching the patient. Medication administration is an important step in medicinal therapy. There are no additional opportunities to detect potential medication errors beyond this step. Nurses are, in fact, the final "gatekeeper" for the hospitalized patient. Therefore, nurses must be especially vigilant to prevent medication errors. The following are suggested measures nurses can take to prevent medication errors.

1. Review the patient's medication administration record (MAR) to insure that all orders have been transcribed correctly, all information is complete, and there are no therapeutic duplications, allergies, or drug-drug, drug-nutrient or drug-disease interactions. If any questions arise, the order should be verified against the original prescriber order, references and/or colleagues should be consulted as necessary, and the prescriber should be

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**Table 7. Recommendations to assist pharmacists in preventing medication errors**


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- Be available regularly in patient-care areas to serve as a source of information to other healthcare professionals regarding current drug therapies and appropriate use of medications.
- Review the original medication order prior to dispensing the medication, unless emergency circumstances dictate otherwise—screening for prescribing errors, allergies, drug and disease interactions, correct dose, and indication. Dosage calculations should be checked against acceptable dosage ranges. The prescriber of any questionable medication order should be contacted for clarification prior to dispensing the medication.<sup>39</sup> Prior to dispensing the pharmacist should compare the original order with the label and the product being dispensed.<sup>24,40</sup> Most of the functions above can be performed via computers, bar-coding of patient-specific doses, and scanning prior to dose administration.
- Research or request information from the prescriber regarding new or unfamiliar medications, uses, or doses.
- Dispense medications for individual patients in a pre-measured, ready-to-administer form whenever possible.<sup>24</sup> When this is not possible, auxiliary labels should be used to clearly communicate preparation instructions prior to administration. Auxiliary labels should also be used in other situations when they will clearly aid in the prevention of errors.
- Carefully document products used and steps and calculations performed in the preparation or manufacture of a drug product. This is primarily for high alert drugs, those that have the greatest consequences of error. For these medications, it is particularly important that an independent double-check be used for all calculations.
- Carefully document all verbal orders received from prescribers as new orders, renewals, or corrections to a new order. This should be done immediately after receiving and carefully verifying the order by repeating it back to the prescriber, spelling the drug name and any other word that might have been misheard and restating numbers that may be confused, such as those in the teens.<sup>38</sup>
- Ensure that medications arrive in the patient-care area in a timely fashion following the receipt of the order. If medication delivery will be delayed for any reason, such as the need to resolve a problem with the order, the nurse caring for the patient should be notified of the delay and the reason.
- Counsel patients and their caregivers, verifying that they understand the name, purpose, route of administration, dose, dose frequency, potential adverse effects, and how adverse effects might be managed for each medication they are receiving.

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contacted if a change is required.

2. Verify orders, screen for prescribing errors, allergies, drug-drug, drug-nutrient, and drug-disease interactions, and appropriateness of dose and indication. Dosage calculations should be double-checked. Any potential problems should be resolved prior to administering the medication.<sup>24,41</sup>
3. Carefully document all *verbal* orders received from prescribers as new orders, renewals, or

corrections to a new order. This should be done immediately after receiving the order. The order should be carefully verified by repeating it back to the prescriber, spelling the drug name and any other piece of information that might have been misheard. The nurse should also restate numbers that may be confused, such as those in the teens.<sup>38</sup>

4. Prior to medication administration, compare the first dose of medication dispensed with

the original prescriber order and the medication administration record (MAR). The nurse should confirm that the correct medication, dose, and dosage form have been provided. Obviously, any concerns (e.g., the need for multiple dosage units to obtain a single dose; inappropriate dosage form or volume for the individual patient) should be addressed prior to administration of the drug. Subsequent to this dose, medications should be verified against the MAR. Transcribed MARs for future doses must be verified with the old MAR to assure accurate transcription. Medications should not be removed from packaging until they are ready for administration.<sup>21</sup>

5. Verify patient identity prior to administration of any medication.<sup>21</sup> When appropriate and reasonable, patients or caregivers should be told the name and purpose of each medication when each dose is given. This aids in patient education and gives the patient an opportunity to become more involved in his or her care and prevent possible medication errors. If the patient questions a medication, the nurse should listen, answer questions, and (if appropriate) verify the order and product before administering the medication.
6. Administer all doses at scheduled times, unless the patient is unavailable or there are problems with the order or medication that need to be resolved. Medication administration should be documented as soon as it is completed; thereby, recording the actual time the dose was administered. An electronic medical administration record (MAR) with scannable bar-coded patient-specific doses will greatly reduce administration errors.
7. Contact a pharmacist regarding missing doses, rather than "borrowing" from another patient or stockpiling unused medications.
8. Understand the correct operation of medication-administration devices and be aware of the potential for errors that may occur with the use of these devices (e.g., programmable pumps).
9. Counsel patients and their caregivers, verifying that they understand the name, purpose, route of administration, dose, dose frequency,

common adverse effects, and how adverse effects might be managed for each medication they are receiving. Provide drug information at discharge and assure understanding by the patient/caregiver.

### *Recommendations for Patients and Caregivers*

All caregivers and all but the youngest patients should be given the opportunity to be involved in the patient's drug therapy. To actively participate in their therapy, the patient or caregiver must be informed about every medication prescribed and administered and must be encouraged to ask questions and raise concerns. A well-informed patient or caregiver feels less helpless in a situation that they do not control and also provides an extra opportunity to prevent the occurrence of a medication error. Patient and/or caregiver education should be considered a standard of care and policies should be created to increase the involvement of these individuals in treatment. The following recommendations are offered to patients and caregivers to assist them in optimizing their drug therapy and preventing medication errors (Table 8).<sup>10</sup>

An important part of patient education is discharge counseling. Continuity of care should be stressed. Some ways that this may be accomplished include:<sup>42</sup> 1) to ensure availability of similar products and concentrations that were used during hospitalized dispense discharge prescriptions through an outpatient pharmacy affiliated with the institution; and 2) having caregivers fill discharge prescriptions at the outpatient pharmacy they normally patronize so that errors might be discovered and discharge counseling can be customized to the products and concentrations dispensed.

### CONCLUSIONS

This document makes recommendations for the prevention of medication errors in pediatric patients, incorporating the suggestions of health-care professionals involved in the daily treatment of this patient population. By working together as a patient-care team medication error occurrence can be minimized through education,

**Table 8.** Recommendations to assist patients and caregivers in optimizing drug therapy and preventing medication errors

- Know the name, dose, strength or concentration, dosage schedule, purpose, and appearance of all medications taken by or administered to the patient.
- Carry an up-to-date list of medications they are taking, including prescription, nonprescription, and homeopathic medicines; vitamins and minerals; herbal products and home remedies, in addition to a list of any medications they cannot take and the reasons why these medications cannot be taken. The information on these lists should be given to the healthcare professionals involved in the patient's care.
- Understand any special storage, preparation, measuring, and administration techniques required to obtain the maximum benefit from the drug therapy. A healthcare professional involved in the patient's care should observe the patient's technique and make suggestions to improve or correct.
- Understand the importance of taking or giving medications as directed and for the prescribed length of time.
- If the patient is of sufficient age, or when the caregiver is present at medication administration time, ask to be shown each medication and told the purpose of each.
- Actively participate in their drug therapy by asking questions and participating in making decisions.
- Question anything that seems unusual. A potential error may be prevented by a single question.

development of effective systems, individual efforts, and by healthcare professionals. When errors do occur, it is important to first minimize the effect on the patient and then to learn from the error and improve the system to prevent similar occurrences in the future.

#### ACKNOWLEDGEMENTS

We appreciate the participation of Yvonne D'Antonio, PharmD, Safe Medication Management Fellow at the Institute for Safe Medication Practices and the Center for Proper Medication Use for developing the framework used to stimulate discussion at the ASHP conference. We thank Dean Bennett, RPh, and Theresa Forbes, PharmD, at the Alfred I. duPont Hospital for Children, Wilmington, Delaware, for their review and comments of the final guidelines.

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